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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,075	09/22/2004	Raoul Donath	001227/0152	1247

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NEW YORK, NY 10038

EXAMINER

WOODALL, NICHOLAS W

ART UNIT	PAPER NUMBER
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3733

MAIL DATE	DELIVERY MODE
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06/19/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/509,075	Applicant(s) DONATH, RAOUL	
	Examiner Nicholas Woodall	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 October 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This action is in response to applicant's amendment received on 03/29/2007.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 19 and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by Schaffler-Wachter (U.S. Patent 6,402,752 B2).

Regarding claim 19, Schaffler-Wachter discloses a device comprising a connection element, a sealing cap, and a tensioning means capable of engaging the rear end of the sealing cap. The connection element includes a central axis, an external surface, and upper end, a lower end, a cavity extending coaxially along the central axis from the upper end to the lower end having a reduced diameter portion at the lower end forming at least one shoulder therein, and a channel passing through the connection element transversely to the central axis for receiving the longitudinal carrier. The sealing cap includes a front end, a rear end, a second cavity opening at the front end capable of receiving the connection element, and a second channel extending transversely to the central axis and opening towards the front end of the sealing cap. The external surface of the connection element has a plurality of bulges aligned parallel to the central axis.

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The internal surface of the sealing cap includes a plurality of depressions aligned parallel to the central axis and complementary to the plurality of bulges, wherein the sealing cap is capable of engaging the connection element by a snap-fit connection. Regarding claim 20, Schaffler-Wachter discloses a device wherein the bulges and the depression have a saw-tooth shaped profile.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bono (U.S. Patent 6,755,829) in view of Katz (U.S. Patent 5,989,254).

Regarding claim 1, Bono discloses a device comprising a connection element, a sealing cap, and a tensioning means (see Figures 1 and 2 below). The connection element includes a central axis, an external surface, and upper end, a lower end, a cavity extending coaxially along the central axis from the upper end to the lower end with a reduced portion at the lower end forming at least one shoulder therein, and a channel passing through the connecting element transversely to the central axis. The sealing cap includes a front end, a rear end, a second cavity opening at the front end, and a second channel extending transversely to the central axis and opening towards the front end of the sealing cap. The external surface of the connection element and the internal surface of the second cavity formed in the sealing cap contain complementary

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arresting means. The complimentary arresting means extend continuously, concentrically, and non-threadingly around the central around the central axis on the connection element external surface and the sealing cap internal surface, wherein the first and second channels interrupt the continuity of the arresting means. Regarding claim 2, Bono discloses a device wherein the arresting means are arranged orthogonal to the central axis on the periphery of the connection element and on the periphery of the second cavity in the sealing cap. Regarding claim 3, Bono discloses a device wherein the arresting means includes a plurality of bulges formed on the external surface of the connection element and a plurality of complementary depressions formed in the second cavity of the sealing cap, wherein the plurality of bulges and the plurality of depressions are aligned parallel to the central axis. Regarding claim 4, Bono discloses a device wherein the shoulder has a level-bearing surface of a circular-ring shape. Regarding claim 5, Bono discloses a device wherein the sealing cap further includes two slots arranged orthogonal to the second channel, the slots extending from the front end of the sealing cap. Regarding claim 6, Bono discloses a device further comprising a bone fixation means having a central axis, a front segment, and an axially adjoining rear segment, wherein the rear segment has a cylindrical form and the front segment extends through the lower end of the connection element. Regarding claim 7, Bono discloses a device wherein the bone fixation means is a pedicle screw with a screw shaft having an external thread and a screw head at an end thereof. Regarding claim 8, Bono discloses a device wherein the tensioning means comprises a setscrew. Regarding claims 1 and 9, Bono disclose the invention as claimed except for the device

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comprising a securing means (claim 1), wherein the securing means includes a pin and hole configuration (claim 9). Katz teaches a device comprising a securing means that includes a pin and hole configuration in order to restrain the connecting member to the pedicle screw (column 2 lines 61-67). It would have been obvious to one having ordinary skill in the art at the time the invention was made to manufacture the device of Bono with a securing means in view of Katz in order to restrain the connecting member to the pedicle screw.

Figure 1

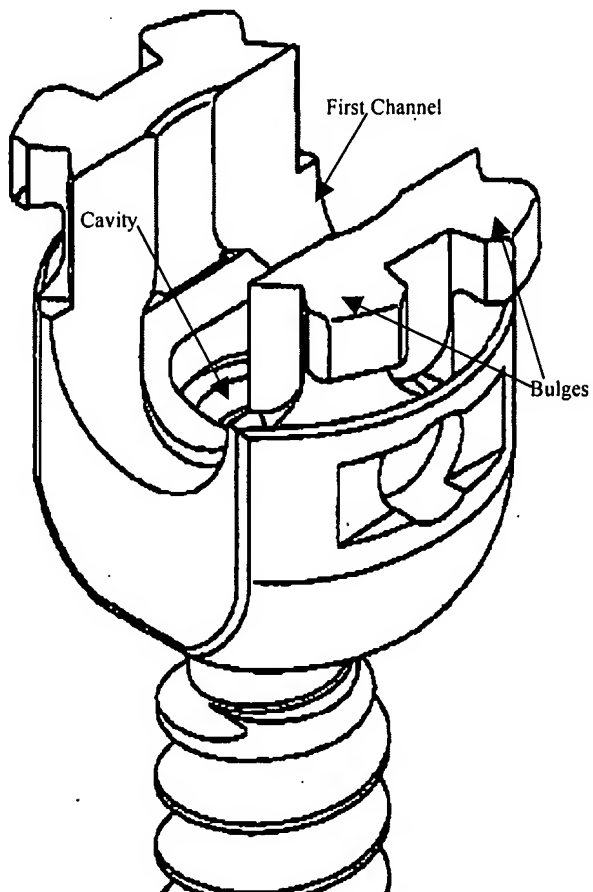
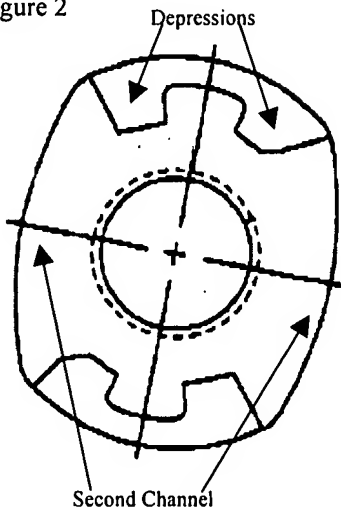


Figure 2



6. Claims 1-8 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bono (U.S. Patent 6,755,829) in view of Nicholas (U.S. Patent 6,090,111).

Regarding claim 1, Bono discloses a device comprising a connection element, a sealing cap, and a tensioning means (see Figures 1 and 2 below). The connection element includes a central axis, an external surface, and upper end, a lower end, a cavity extending coaxially along the central axis from the upper end to the lower end with a reduced portion at the lower end forming at least one shoulder therein, and a channel passing through the connecting element transversely to the central axis. The sealing cap includes a front end, a rear end, a second cavity opening at the front end, and a second channel extending transversely to the central axis and opening towards the front end of the sealing cap. The external surface of the connection element and the internal surface of the second cavity formed in the sealing cap contain complementary arresting means. The complimentary arresting means extend continuously, concentrically, and non-threadingly around the central around the central axis on the connection element external surface and the sealing cap internal surface, wherein the

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first and second channels interrupt the continuity of the arresting means. Regarding claim 2, Bono discloses a device wherein the arresting means are arranged orthogonal to the central axis on the periphery of the connection element and on the periphery of the second cavity in the sealing cap. Regarding claim 3, Bono discloses a device wherein the arresting means includes a plurality of bulges formed on the external surface of the connection element and a plurality of complementary depressions formed in the second cavity of the sealing cap, wherein the plurality of bulges and the plurality of depressions are aligned parallel to the central axis. Regarding claim 4, Bono discloses a device wherein the shoulder has a level-bearing surface of a circular-ring shape. Regarding claim 5, Bono discloses a device wherein the sealing cap further includes two slots arranged orthogonal to the second channel, the slots extending from the front end of the sealing cap. Regarding claim 6, Bono discloses a device further comprising a bone fixation means having a central axis, a front segment, and an axially adjoining rear segment, wherein the rear segment has a cylindrical form and the front segment extends through the lower end of the connection element. Regarding claim 7, Bono discloses a device wherein the bone fixation means is a pedicle screw with a screw shaft having an external thread and a screw head at an end thereof. Regarding claim 8, Bono discloses a device wherein the tensioning means comprises a setscrew. Regarding claims 1-8 and 10, Bono discloses the invention as claimed except for the device comprising a securing means (claim 1), wherein the securing means includes a snap-ring and groove configuration (claim 10). Nichols teaches a device comprising a securing means that includes a snap-ring and groove configuration in order to retain the

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fastener (column 4 lines 5-15). It would have been obvious to one having ordinary skill in the art at the time the invention was made to manufacture the device of Bono with a securing means in view of Nichols in order to retain the fastener.

7. Claims 11-15 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schaffler-Wachter (U.S. Patent 6,402,752 B2).

Regarding claims 11-15 and 18, Schaffler-Wachter discloses the invention as claimed, as discussed above, except for the plurality of projections and recess being axially displaced along the external surface of the connection element and the internal surface of the sealing cap. It would have been obvious to one having ordinary skill in the art at the time the invention was made to manufacture the device of Schaffler-Wachter further comprising a plurality of projections and recesses axially displaced along the external surface of the connection element and the internal surface of the sealing cap, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

8. Claims 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schaffler-Wachter (U.S. Patent 6,402,752) in view of Katz (U.S. Patent 5,989,254).

Regarding claims 16 and 17, Schaffler-Wachter discloses the invention as claimed except for except for the device comprising a securing means (claim 16), wherein the securing means includes a pin and hole configuration (claim 17). Katz teaches a device comprising a securing means that includes a pin and hole configuration in order to restrain the connecting member to the pedicle screw (column 2 lines 61-67). It would have been obvious to one having ordinary skill in the art at the

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time the invention was made to manufacture the device of Schaffler-Wachter with a securing means in view of Katz in order to restrain the connecting member to the pedicle screw.

Response to Arguments

9. Applicant's arguments with respect to claims 1-20 have been considered but are moot in view of the new ground(s) of rejection. The examiner has presented new grounds of rejection for claims 1-20 as discussed above. Applicant's arguments that Schaffler-Wachter does not disclose the bulges and slots are not parallel to the central axis is not persuasive. If the central axis were projected to the edge of the bulges and depressions, the examiner believes that the edge of the bulges and the depressions are parallel to the central axis of the device. The applicant amended independent claim 1, which necessitated the new grounds of rejection making this office action **FINAL**.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892 for cited references the examiner felt were relevant to the application.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within


TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicholas Woodall whose telephone number is 571-272-5204. The examiner can normally be reached on Monday to Friday 8:00 to 5:30 EST..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

now


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SUPERVISORY PATENT EXAMINER